

12/16/05

**Department of Veterans Affairs
Human Research Protection Program Accreditation Contract**

The new contract for accreditation of VA Human Research Protection Programs (HRPPs) has been awarded to The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) effective December 1, 2005. We are very proud of VA facilities' accomplishments in HRPP accreditation under the VA contract with the National Committee for Quality Assurance (NCQA), and look forward to the next phase with AAHRPP. We will do everything in our power to see that all VA facilities have the help they need to pass AAHRPP accreditation.

Transition Communication

- Because of the nature of the VA contracting process, we did not have an opportunity to begin discussing the details of the transition with AAHRPP until after the contract was awarded on December 1. Since then we have been working hard on ensuring a smooth transition.
- The first field conference call to discuss the transition plan and answer questions was December 16, 2005. We had 177 participants.
- The next field conference call will be in the last half of January 2006. Dr. Marjorie Speers, Executive Director of AAHRPP, will join us to review specifics of the AAHRPP process including which AAHRPP domains apply to different VA HRPP configurations (e.g., a VA that uses another VA's IRB or an affiliate's IRB).
- We will announce a regular conference call schedule early in 2006.
- The proceedings from all of the conference calls will be posted on the PRIDE web site at www.va.gov/resdev/programs/PRIDE.

Implications of the new contract with AAHRPP

- AAHRPP was founded in 2001 solely for the purpose of accrediting human research protection programs, so its leadership and staff are very well-grounded in human research protection.
- AAHRPP has the flexibility to handle *all* configurations of VA HRPPs, including small research programs and regional IRBs. All configurations are eligible to apply for a full 3 years AAHRPP accreditation. There is no longer a requirement for at least 8 new protocols per year to become accredited.
- AAHRPP's site visit process provides a real time review of the HRPP and gives credit for recent program improvements. For example, AAHRPP will accept changes made after its site visit.
- AAHRPP does not have a 12 month look back period. For example, it requests only 3 sets of approved minutes for each IRB, not 12 months of minutes.

- AAHRPP provides a more comprehensive HRPP review including assessment of investigators and subjects, and it emphasizes continuous quality improvement.
- The AAHRPP process also emphasizes education, so AAHRPP will provide support and guidance throughout the application process.
- AAHRPP is the entity that accredits academic HRPPs. 45 VA facilities use 38 academic affiliates' IRB(s). 28 of the 38 already plan on AAHRPP accreditation. For these VAs, the use of the same accrediting entity has the potential to further strengthen the VA-affiliate relationship.

Logistics

Transition from NCQA

- The NCQA contract ends on January 31, 2006.
- 2007 and 2008 NCQA accreditation expiration dates will be honored.
- Annual reports and interim reports (e.g., changes in the HRPP or violation of any federal or state laws) should be submitted to Dr. Marisue Cody in COACH, not to NCQA, after January 31, 2006. The NCQA annual report form should be used. It will be posted on the PRIDE web site.
- VA facilities that underwent the NCQA INR-only survey and whose affiliates have not become accredited by AAHRPP by January 31, 2006, will have no accreditation status since their becoming accredited by NCQA was contingent on their affiliate's accreditation. Because NCQA will not have a contract with the VA after January 31, 2006, it will not be able to grant accreditation status to those VA facilities. We will contact each of the affected facilities and deal with the issues on an individual basis. It is important to recognize that all of the work that went into preparation for the NCQA INR-only survey will provide a very strong foundation for the AAHRPP application.

Transition to AAHRPP

- AAHRPP will use its current standards. These standards do not change very often. They will be reviewed, and possibly revised, in 2008. If they are revised at that time, the revised standards will be released 2010.
- AAHRPP has revised its' evaluation instrument to include VA policies. The revised evaluation instrument will be posted on the AAHRPP web site (www.aahrpp.org) in January.
- AAHRPP standards, the current evaluation instrument (without the VA-specific modifications), information on how to apply, and tip sheets can be found on the AAHRPP web site at www.aahrpp.org.
- Dr. Cody is creating a cross-walk between NCQA and AAHRPP standards. This will be posted on the PRIDE web site in January 2006.
- The only 2 differences between the AAHRPP accreditation of VA facilities and non-VA facilities will be:
 - 1) The VA will not use the option for AAHRPP preliminary applications, only formal applications.
 - 2) The AAHRPP evaluation instrument will include VA policies.

- The AAHRPP process includes a self-evaluation, an application, and then a site visit.
- At the exit meeting of the site visit, the site visitors will tell you what needs to be fixed so you can start working on it. You will get a draft report within 30 days, and have 30 days to respond to the draft report.

Affiliates

- AAHRPP will do its best to coordinate site visits for VAs and their respective affiliates, but this will depend on cooperation from the affiliate.
- AAHRPP will offer some VA sites the option of applying before the NCQA expiration date so that the VA can coordinate its application with its affiliate's.
- AAHRPP will be able to accredit VA facilities whose affiliates do not choose to apply for AAHRPP accreditation if the affiliate provides the information AAHRPP requires to accredit the VA facility.

Scheduling

- The date for having all VA facilities' HRPPs accredited and on a regular 3-year cycle will be pushed back to the end of CY 2007. ALL VA FACILITIES' HRPPs MUST BE ACCREDITED BY EITHER NCQA OR AAHRPP BY THE END OF CY 2007.
- We will work with AAHRPP to see that facilities whose NCQA applications were due in 2006 are re-scheduled allowing reasonable time for preparation. However, *all sites that have not yet been surveyed by NCQA will still have to submit their applications to AAHRPP in 2006.*
- PRIDE will be doing all the scheduling for AAHRPP applications.
- Paula Sclichter from PRIDE will be calling you to get information so we can assign you an application date.
- We will have the schedule for all 2006 AAHRPP applications finalized by the end of January 2006.
- The AAHRPP application process will start by June 2006.
- VA facilities that feel ready are encouraged to submit their applications before June 2006.
- In general, AAHRPP estimates a site should start the process 6 months prior to the Council decision for first time accreditation, and 9 months ahead for re-accreditation.

Training

- AAHRPP will hold 5 1-day Getting Started Workshops for VA facilities. The first will be in early 2006. VA facilities will be assigned to the workshops based primarily on when their AAHRPP applications are due (e.g., the VAs that plan to apply first will be invited to the first Workshop).
- AAHRPP's annual meeting will be February 26-28, 2006, in Phoenix, Arizona. We have been invited to work with AAHRPP on VA-specific programming for this meeting. ORD will be able to pay for up to 99 VA

staff to attend this year. We will prioritize who ORD pays for by when AAHRPP applications are due. Additional VA staff may attend if their local facilities pay. VA staff may qualify for a reduced registration rate. We will provide more information as it becomes available.

Questions

Questions can be addressed to K. Lynn Cates, MD (lynn.cates@va.gov or 202-254-0282) or Marisue Cody, PhD, RN (marisue.cody@va.gov or 202-254-0271).